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10/518,728	01/23/2006	Wenquan Fang	SZ001-04	3184
65584 7590 979220098 BARRON & YOUNG INTELLECTUAL PROPERTY HKPC BUILDING, 5TH FLOOR			EXAMINER	
			MI, QIUWEN	
78 TAT CHEE KOWLOON,	AVENUE		ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/518,728 FANG, WENQUAN Office Action Summary Examiner Art Unit QIUWEN MI 1655 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 11 June 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-10 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-10 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

Applicant's amendment in the reply filed on 6/11/08 is acknowledged. Any rejection that is not reiterated is hereby withdrawn. Claims 1-10 are pending. Claims 1-10 are examined on the merits.

Claim Rejections -35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 10.2 of this title, if the differences between the subject matter as would to be patented and the prior at are such that the subject matter as whole would have obobvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Zuo (WO 01/76613 A1), Kim (US 4,696,818), Wen (US 5,198,230), Zhou (US 6,416,806), Oh (KR 2000072102), and Chang et al (US 5,552,404).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 6/11/2008, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Zuo teaches a composition has effects on helping narcotic addicts to abstain physiological dependency and psychological dependency comprising root of Panax ginseng, root of Aconitum carmicharli Debx, skin (stem bark) of Cinnamomum cassia, stem (tube) of Corydalis turtschaninovii, root of Salvia militorrhiza, Ziziphus jujuba Mill, and root of Glycyrrhiza

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uralensis (see Abstract, full translation has been ordered). Zuo also teaches that Ziziphus jujube
"ren" (seed) is part that is being used (see Chinese Abstract). Zuo further teaches that the
composition can be in the pharmaceutical forms, such as tablet, powder, capsule, decoction, and
injections, with carriers/excipients (page 5, lines 1-10). At last Zuo teaches extracting volatile
oils from raw materials such as Cinnamomum cassia with conventional water distillation (page 6,
last paragraph), and extracting raw materials using water decoction (page 6, 1st paragraph), and
70% ethanol reflection (page 6, 3rd paragraph) (see the full translation attached).

Zuo does not teach a composition with the incorporation of Angelica polymorpha,

Cyperus rotundus, Paeonia lactiflora, Schizandra chinensis, and Tween 80 into the composition.

Kim teaches a composition for treatment during withdrawl from drug dependency comprising Radix (root) Angelica sinensis (synonym of Angelica polymorpha), and Cyperus rotundus.

Wen teaches a composition for the treatment of addictive disease comprising *Buthus* martensii kirsch and *Aconitum carmichaeli* etc (col 2, lines 45-50).

Zhou teaches a composition for caffeine addiction comprising extracts *Paeonia lactiflora*, and Schizandra (the same as *Schizandra chinensis* fruit).

Oh teaches a composition for stop smoking (narcotic addiction) comprising Amonum villosum (see full translation attached).

Chang et al teach a composition for treating drug addiction comprising Tween 80. Chang et al also teach adjust pH of the composition to 4-7.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for drug addiction. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Zuo, Kim, Wen, Zhou, Oh, and Chang et al since all of them teach compositions for treating drug addiction individually in the

art. Since all the compositions yielded beneficial results in treating drug addiction, one of ordinary skill in the art would have been motivated to make the modifications. It is well known in the art that Amomum villosum fruit, Schizandra Chinese fruit, and Paeonia lactiflora root are the parts of the herb that are being used. Regarding the limitation to the amount of the ingredients in the composition, the result-effective adjustment in conventional working parameters, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on the crop and amount of insect control that is needed.

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "To reach a proper determination under 35 U.S.C. § 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis

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of the facts gleaned from the prior art alone, without the guidance of the Applicant's application.

Applicant respectfully submits that by relying on four or more references to reject the claims of the present invention, the Examiner has committed impermissible hindsight reconstruction based on the road map provided by the present invention" (page 5, last paragraph bridging page 6).

In response to Appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In addition, the basis for the 103 resides in the knowledge that each individually claimed component was already known in the art for treatment of drug addiction and that one of ordinary skill in the art, having the above-cited references before him or her would have recognized the advantageous nature of combining the ingredients in order to achieve an additive effect on treatment of drug addiction.

Applicant argues that "Zuo fails to disclose all the limitations recited in claim 1.

Specifically, Zuo fails to teach or suggest "Amomum villosum fruit 38-112~; Schizandra chinensis fruit 31-93g; Angelica polymorpha root 56-168g; Paeonia lactiflora root 75-225g;

Cyperus rotundus root 62-187g; Buthus martensii Karsch 31-93g," In fact, Zuo teaches away

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from using the above medicinal materials to curing a withdrawal symptom of addictive drug reliers. Zuo even teaches no suggestion or motivation to use such medicinal materials" (page 6. last paragraph). Applicant states that "Zuo teaches an extract for abstaining from narcotics, which comprises: 45-60 portions of component A, one or more substances selected from Hominis Placenta, Flower of Daturu metel L, toxin of Fugu ocellatus and/or toxin of Naja naja; 15-30 portions of component B; one or more substances selected from Root of Panax ginseng, Ginseng Radix Ferum, Ginseng Radix Coreensis and/or Panacis Quinquefolii Radix; 6-9 portions of component C, one or more substances selected from Root of Aconitum carmicharli Debx., and/or Skin of Cinnamomum cassia Presl; 30-60 portions of component D. Chelidonium majus L; 9-15 portions of component E, Stem of Corydalis turtschaninovii; component F, 9-15 portions bezoar and/or 0.5-3.0 portions of borneol; 12-15 portions of c0mponent G, one or more substances selected from Fruit of Cannabis sativa L. and/or Fruit of Biota orientalis (L) Endl; 6-12 portions of component H, one or more substances selected from Stem of Aipinia officinarum Hance and/or Stem of Zingiber officinale Rosc.; 15-30 portions of component I, red -crowned crane; 15-30 portions of component J, one or more substances selected from Ziziphus jujuba Mill, and/or Fruit of Ziziphus jujuba Mill.; 6-10 portions of component K, one or more substances selected from Glycyrrhiza and Honey-Fried Root of Glycyrrhiza. One of ordinary skill in the art, having read the teaching of Zuo, will not use the medicinal materials at least comprising "Schizandra chinensis fruit, Angelica polymorpha root, Paeonia lactifiora root, Cyperus rotundus, Buthus martensii Karsch, Amomum villosum fruit." The Chinese medicine of the present invention is prepared with panax ginseng root and aconitum carmichaeli debx root, which is the warm components. The two can nourish spleen and kidney, nourish premordial

energy greatly, and consolidate origin, so they are dominant drugs of the prescription.

Cinnamomum cassia stem bark, amomum villosum fruit and schizandra chinensis fruit are mixed to assist the panax ginseng root and aconitum carmichaeli debx root to nourish spleen and kidney more effectively, and they three drugs also have efficacies such as relieving darrhea, arresting sweating, arresting seminal emission and tranquilization. Additionally, angelica polymorpha root and paeonia lactiflora root are mixed therein to assist the basic remedy to nourish female blood, invigorate the circulation of blood, activate the channels, nourish the liver to relieve pain and relieve convulsion. Moreover, salvia miltiorrhiza root and zizyphus jujuba seed are mixed therein to assist the basic remedy to relief fidget, enriching the blood, soothe the nerves, arresting sweating and hidroschesis. Furthermore, glycyrrhiza uralensis root is mixed therein to supplement vital energy, invigorate the middle-warmer, nourish the lung arrests cough, antidote the poison, assuage pain and concoct the property of the medicine, and to be a conducting drug. Cyperus rotundus root can be used to regulate Qi and solve siltation, regulate menstruation and activate pain. For woman addicts, it can be used to treat menoxenia and amenorrhea. Thus, Zuo teaches away from the invention recited in claim 1 of the present invention" (page 7 bridging page 8).

This is not found persuasive. Choosing from a finite number of predictable solutions would have been obvious because a person of ordinary skill has good reason to pursue the known options with his or her technical grasps. If this leads to the anticipated success, it is likely that the product is not of innovation, but of ordinary skill and common sense. In addition, Applicant argues that the cited reference teaches away from the claimed invention. Just because the cited reference does not teach the mechanism in the current specification does not constitute a teaching

away as the cited reference does not criticize, discredit, or otherwise discourage the composition claimed. Further, It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed components are art-recognized result effective variables because they have the ability to treat drug addiction, which would have been routinely determined and optimized in the pharmaceutical art.

Applicant argues that "Kim teaches a method for treatment of opium, morphine or cocaine dependent human subjects comprising the step of orally administering during the period of drug withdrawal a composition comprising Radix angelica sinensis, Herba pogostemi, Cyperus rotundus and Swquama manitis pendactilae in unit dosage form. Kim does not teach or suggest what are missing in Zuo, i.e., Radix angelica sinensis and Cyperus rotundus. There is no suggestion or motivation for the person of ordinary skill in the art to combine the two references. Even Zuo and Kim are combined, the combination of Zuo and Kim does not teach or suggest all the limitations of claim 1 and cannot render claim 1 obvious" (page 8, 3rd paragraph). Applicant states that "Zhou teaches a caffeine replacement composition, comprising: Ginkgo biloba extract and kudzu extract wherein said Ginkgo biloba extract and said kudzu extract are present at a ratio by weight of said Ginkgo biloba extract to said kudzu extract of between about 0.1 and about 4, and Paconia lactiflora and Schizandra. Zhou does not teach or suggest what are missing in the

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combination of Zuo, Kim and Wen, i.e., Paeonia lactiflora and Schizandra. There is no suggestion or motivation for the person of ordinary skill in the art to combine the four references" (page 9, 2nd paragraph). Applicant further argues that "Oh teaches a composition for stop smoking comprising Amomum villosum. Oh does not teach or suggest what are missing in the combination of Zuo, Kim, Wen and Zhou, i.e., Amomum villosum. There is no suggestion or motivation for the person of ordinary skill in the art to combine the five references" (page 9, 3rd paragraph).

This is not found persuasive. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of invention. In addition, KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision Ex parte Smith, --USPQ2d--, slip op. at 20 (Bd. Pat. App.& Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Applicant argues that "Wen teaches a method for treating addiction prevalent in China that six Aconitum carmichaeli; Flow Daturae, Buthus martensii karsch, Cinnbaris, which are herbs of prisoners, and swallow. Wen does not teach or suggest what are missing in the combination of Zuo and Kim, i.e., Buthus martensii karsch and Aconitum carmichaeli. There is no suggestion or motivation for the person of ordinary skill in the art to combine the three

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references. Even if the Zuo, Wen and Kim are combined, an important component of these compounds is Flow Daturae, which has a chemical component of scopolamine and would be used to restrain the cerebral cortex of the drug relier, produce mild anesthetic effect, stimulate respiratory center, and accelerate the metabolism and excretion of morphine. It is known to the person of ordinary skill in the art, the Flow Daturae L has strong addiction and poisonous side-effect, and its dosage should be strictly controlled. The present invention is a safe Chinese medicine preparation without such poisonous medicinal materials. Therefore, a combination of Zuo, Kim and Wen does not teach or suggest all the limitations of claim 1 and cannot render claim 1 obvious (page 8, last paragraph bridging page 9).

This is not found persuasive. Aconitum carmichaeli Debx root in the current claim is also very toxic. One of the ordinary skills in the art would know how to control the dosage of a poisonous herbal material in the composition to limit the side effect of the component.

Applicant argues that "Even the five references are combined, they fail to teach or suggest all the limitations of claim 1. The combination of the five reference teach a compound comprising: one or more substances selected from Hominis Placenta, Flower of Datura metel L, toxin of Fugu ocellatus and/or toxin of Naja naja; Chelidonium majus L; bezoar and/or borneol; one or more substances selected from Fruit of Cannabis sativa L. and/or Fruit of Biota orientalis (L) Endl; one or more substances selected from Stem of Aipinia officinarum Hance and/or Stem of Zingiber officinale Rosc.; Aconitum carmichaeli Debx root; Cyperus rotundus root; Angelica polymorpha root; Cyperus rotundus root; Buthus martensii Karsch; Amomum villosum fruit; Schizandra chinensis fruit; Paeonia lactiflora root; Herba pogostemi; Swquama manitis pendactilae; vermilion and Panax ginseng root. Then comparing with this compound, the

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Chinese traditional medicine preparation of the present invention does not comprises; one or more substances selected from Hominis Placenta, Flower of Datura metel L, toxin of Fugu ocellatus and/or toxin of Naja naja; Chelidonium majus L; bezoar and/or bomeol; one or more substances selected from Stem of Aipinia of ficinarum Hance and/or Stem of Zingiber officinale Rosc.; one or more substances selected from Stem of Aipinia officinarum Hance and/or Stem of Zingiber officinale Rosc.; Herba pogostemi; Swquama manitis pendactilae. The person of ordinary skill in the art knows that Flower of Datura metel L has strong addiction and poisonous side-effect, and the toxin of Fugu ocellatus and toxin of Naja naja are all neurotoxin which is hard to obtain and costly, and their dosage should be strictly controlled. The person of ordinary skill in the art knows Fruit of Cannabis sativa L. has component of toadstool choline and hydroxybenzene, which may operate a muscarinic action on central nervous and bring in toxic reaction. Besides, traditional Chinese medicine considers if a person has a long-term freak-out, the abnormal of Qi and Blood may be caused. Lingering of the symptom caused by the long-term freak-out is bound to be of deficiency and siltation. The pathogenic region is in the blood vessel, the pathogenic root is in the kidney and brain.

This is not found persuasive. Since the current claims use open language "comprising", it does not prelude other components that are not in the claims.

The Chinese medicine preparation of the present invention adapts to
the drug relief who has insufficient spleen and kidney, insufficient vital energy and blood, blood
stasis and vital energy retardation and evil poison disordering heart. Such pathogenesis belongs
to false and true met and cold and heat interwoven, so according to the principle of Chinese
medicine dialectical abstinence from drugs, the treatment principle may be adopted which has

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the efficacy of warming spleen and kidney, benefiting vital energy, enriching the blood, promoting flow of gi and blood circulation, relieving mental stress and abstinence from drugs. Furthermore, the curative effect of the medicinal materials exert optimally, when certain medicinal materials are combined in certain ratio. The Chinese medicine of the present invention is prepared with panax ginseng root and aconitum carmichaeli debx root, which is the warm components. The two can nourish spleen and kidney, nourish premordial energy greatly, and consolidate origin, so they are dominant drugs of the prescription. Cinnatnomum cassia stem bark, amomum villosum fruit and schizandra chinensis fruit are mixed to assist the panax ginseng root and aconitum carmichaeli debx root to nourish spleen and kidney more effectively. and they three drugs also have efficacies such as relieving darrhea, arresting sweating, arresting seminal emission and tranquilization. Additionally, angelica polymorpha root and paeonia lactiflora root are mixed therein to assist the basic remedy to nourish female blood, invigorate the circulation of blood, activate the channels, nourish the liver to relieve pain and relieve convulsion. Moreover, salvia miltiorrhiza root and zizyphus jujuba seed are mixed therein to assist the basic remedy to relief fidget, enriching the blood, soothe the nerves, arresting sweating and hidroschesis. Furthermore, glycyrrhiza uralensis root is mixed therein to supplement vital energy, invigorate the middle-warmer, nourish the lung arrests cough, antidote the poison, assuage pain and concoct the property of the medicine, and to be a conducting drug" (page 9, last paragraph; page 10, page 11, 1st paragraph).

First of all, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the mechanism of each ingredient) are not recited in the rejected claim(s). Although the claims are

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interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Secondly, since the cited references use the claimed components, those claimed components would intrinsically have those functions.

Applicant argues that "Furthermore, the IV clinical experiment has proved that the Chinese medicine of the present invention is a safe Chinese traditional medicine for stopping drug addiction. It is not only can be used to control the acute withdrawal symptoms for stopping opium, but also can be used to control prostrated withdrawal symptoms (insomnia, suspense and pain), and obvious improvement is obtained" (page 11, 2nd paragraph).

This is not found persuasive. According to MPEP 716.02 (a), a greater than additive effect is not necessarily sufficient to overcome a prima facie case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. Ex parte The NutraSweet Co., 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991). In the instant case, Applicant needs to present a side by side comparison between the claimed invention and the closest art to show the allegedly surprising results, mere argument or allegation is insufficient to overcome the obviousness rejection.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

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Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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OM

/Michele Flood/

Primary Examiner, Art Unit 1655